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INTERNAL PROSTHETIC REPLACEMENT OF SKELETAL SEGMENTS LOST IN CO--ETC(U)
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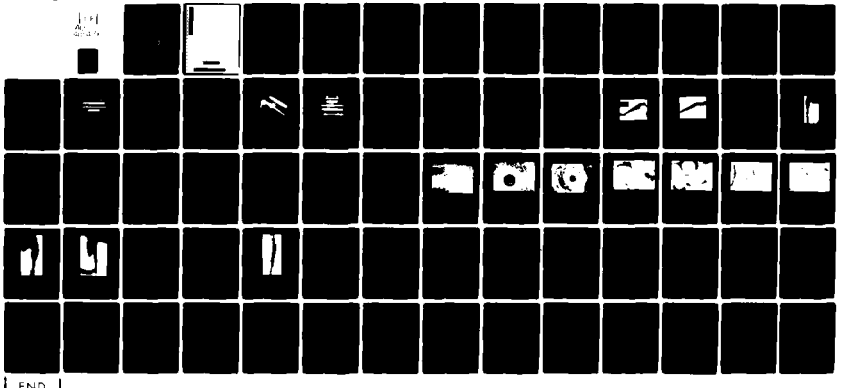

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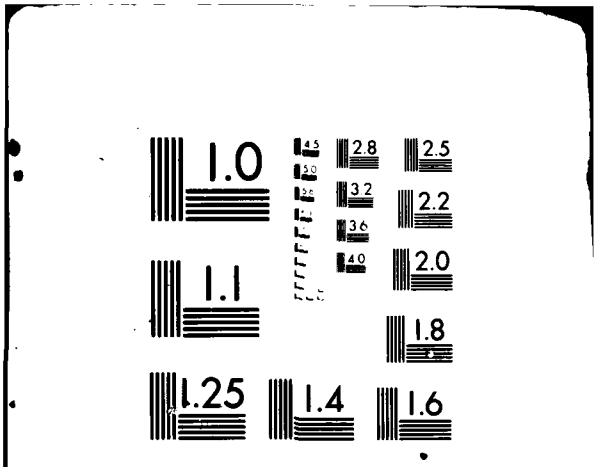
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Summary Report, 1972-1973

on

Internal Prosthetic Replacement of Skeletal Segments Lost in Combat Injuries

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Chicago, Illinois 60680

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I. INTRODUCTION

This report summarizes the results and accomplishments at the end of a second year of research directed toward the development of prostheses and procedures for the internal reconstruction of long bones such that function of limbs is restored.

II. TECHNICAL OBJECTIVE

One of the frequent problems encountered in war casualties involving the extremities is the major loss of segments of long bones or of part of bones and the intervening joint. This is a serious clinical problem, where reconstruction can be extremely difficult or impossible with the existing surgical techniques. In many instances, amputation is the only alternative left to the surgeon. The purpose of this investigation is the development of artificial replacements for large segments of long bones. These replacements would allow reconstruction in cases of major loss of structure in long bones and also in cases where intervening major joints are also involved.

The basic postulate is the development of prosthetic devices capable of becoming integral with the patients skeletal structure. Bone ingrowth into the pores and open spaces of porous material would provide living fixation and incorporation of the implant into the patient's bony structure. The design of these internal prostheses would allow for full, load bearing function during the lifetime of the patient.

The civilian by-product of this development would be the possible use of these artificial bone and bone and joint segments in the reconstruction following radical local excision of tumors of bone of low grade malignancy, such as chondrosarcomas or giant cell tumors of bone.

The development program utilizes the female baboon as a model approximating closely the skeletal anatomy and bone physiology of the human primate. The femur, the tibia and the humerus have been selected as models in long bone reconstruction. Combined reconstruction of the bone segment and the contiguous articulating joint is also being considered.

The individual tasks involved in the research program include:

A. Evaluation of the mechanical and corrosion resistant properties of the materials necessary for the construction of permanent prostheses,

B. Evaluation of tissue response and compatibility of the implant material with the tissues of the host,

C. Continuing evaluation of incorporation of the porous implant materials into the bony structure of the host,

D. Design of synthetic segments of cortical bone,

E. Design of load transfer components of the prosthesis,

F. Design of fixation to the residual bone fragments,

G. Development of clinical procedure for implantation,

H. Development of special tools to be used in the clinical procedure,

I. Clinical and histological evaluation of function and success of the prosthetic device.

III. HYPOTHESIS

The segmental replacement in a long bone as proposed is made possible by the discovery and exploitation by the authors of a class of materials which are singularly compatible with live bone under load-bearing circumstances. A porous metal has been developed which permits invasion of its pores by calcified

tissue and vascular elements such that the result is a composite of the living and the synthetic.

At the same time the porous material can be incorporated with very strong load-sustaining components which prevent the composites from fracturing and permit load transfer. With this concept whose feasibility has been demonstrated we expect the long bone to remodel such that the bone fragments and the segment prosthesis become integral.

This porous metal is manufactured by molding short lengths of fine fibers or wires of metal into precise shapes and bonding the fibers to each other by a sintering thermal treatment. The resultant parts have precision shapes and dimensions and may be assembled by mechanical attachment or welding into prostheses containing solid or tubular elements.

The modeled and sintered fiber has unique attributes. There is about 50% void in the form of interconnecting channels with principal dimensions of the order of 100 microns. Thus it is possible for calcified tissue and vascular elements to enter the external surface and penetrate throughout the bulk of the metallic material. Unlike most porous materials this sintered body is not brittle. It can bend and can sustain substantial impact forces. It cannot fracture in the normal sense of the term. In fact, under extreme distortion it can only tear as would a fabric. The material has remarkable elastic properties which are closely similar to trabecular bone.

In the design of internal prosthetic devices, it is important to consider the deformation properties of biological tissues. As a rule, biological tissues including cancellous bone, cartilage and cortical bone, exhibit much higher compliance than engineering materials such as metals or ceramics. If this matter is not taken into consideration, the mismatch of properties will result in problems at the prosthesis-bone interface resulting in bone

reabsorption and deterioration. In this context the fiber metal sintered composites appear to have a remarkable advantage over other solid or porous materials.

A prosthetic device of this nature would eventually become incorporated into the skeletal structure of the host. However, until such time as bone ingrowth occurs, rigid stability between the implant and the bone is essential. An important part of the development in this research project has been the design and clinical testing of fixation techniques of the prosthetic components to the residual bone fragments.

An important consideration if a joint is to be incorporated into the prosthetic device is the wear of articulating surfaces. Extensive wear studies have been conducted in our laboratories in relation to other research projects and have led to the development of a material of extreme wear resistance. This is a graphite filled, ultra-high molecular weight polyethylene composite that was specifically developed in our research laboratories. The phenomena of wear is highly dependent on apparent contact stresses and this is a finding of extreme importance in consideration for design of artificial joints. Congruous surfaces and large area of contact are of importance in decreasing wear. Through design and material choice, prosthetic devices incorporating major joints can service through a lifetime without biological or mechanical complications.

The evaluation of tissue compatibility is essential if the prosthesis is to function as a permanent implant. Not only must the materials be inert in the body and not induce tissue reaction, but at the same time they must be stable and must maintain their physical and mechanical properties for a lifetime in the hostile environment of the human body.

Manufacturability is another essential consideration in the choice of materials for internal prosthetic devices and the design of internal prostheses. All of these basic points are taken into consideration in the design of the experimental protocols for this research project.

IV. BACKGROUND

A. Previous Work By Others

In the event of loss of a large segment of long bone due to trauma, tumors, or other diseases, there is at present no satisfactory means by which a large gap of bone may be filled with even a moderate degree of success. Since the 17th century, man has tried to replace the large osseous defects mainly with the use of different types of bone grafts. A number of papers have been published on the feasibility of replacing large bony defects in the extremities with autogenous, fresh homogenous, frozen, freeze-dried, decalcified, de-proteinized, heterogenous, autoclaved, and a host of other types of treated bone. After numerous clinical and experimental studies, the majority of these treated bone grafts have disappeared from use. Through extensive experimental work by Burwell[1,2], Heiple[3], Chase and Herndon[4], among others, it has been shown that only autogenous, freeze-dried, or frozen homogenous grafts give promise of better than moderate clinical success in repairing osseous defects. In fairly large clinical series, Wilson[5], Parrish[6], Ottolenghi[7], and Tuli[8], all have reported favorable results with these types of grafts for reconstructing large skeletal defects. However, their success rate is still somewhat less than optimal. In addition, complications are high, such as uncontrollable infection, fracture of the host bone, fracture of the graft, non-union and rejection.

During the past four decades the majority of research has centered around attempts to replace bone with biomaterials. Much of the early work in this vein was done with plaster of paris by Nystrom[9] in 1928, Edberg[10] in 1930, and in 1957 by Peltier[11]. Preliminary results showed that the material was well tolerated and slowly absorbed from the areas of implantation. However, in the application to a large segmental defect, Gourley[12] found that the plaster fragmented easily under minimal stresses. In a later study he attempted to strengthen the plaster by mixing it with epoxy resin. However in this instance the implant provoked a chronic inflammatory response with necrosis and non-union of the segmental defect. Numerous other materials were evaluated for possible use as a substitute for bone. Lottes[13], in France, tried gelatin, Korchin[14] tested starch sponges, Mandarino[15], Salvatore[16] and Redler[17] worked with polyurethane foam, Struthers[18], Bryan and Grindlay[19] all tested polyvinyl sponge. All these materials were deemed inadequate after numerous trials, mainly because of insufficient strength for application to a segmental defect or of the inability of the material to support the desired bony ingrowth.

Other investigators seeing these failures with artificial bone, worked in an opposite vein. They tried to reconstruct defects using solid acrylic or metallic devices relying instead on the intrinsic strength of these materials. However, Gay[20,21], Hankes and Gorman[22] all reported unfavorable results using metallic spacers in dogs, mainly because of inadequate long term immobilization of the implant or fatigue failure of the implant itself.

Since the idea of skeletal prosthetic replacements was still attractive, attempts at reconstruction using solid prostheses in humans were done. Loomis[23], Clark[24], Scales[25], and Wilson[26] all reported reconstruction

of various portions of the skeleton using solid acrylic or stainless steel prostheses. These reports were mainly in the form of case studies and were done with custom designed prostheses. Some short degree of success was claimed for these implants, but no follow-up studies were published and their use was abandoned. Recently, attempts have been made to bridge bone gaps using microporous, resorbable or inert ceramics, impervious glass ceramics and high purity macroporous carbons. Unfortunately, none of these materials has demonstrated a high degree of clinical success in this application. Cerosium[27], a bioceramic developed by Lyman-Smith[28] was used to reconstruct mandibles in 9 human subjects, however, only one implant was deemed successful. Graves[29] bridged a one inch gap in money femurs with a resorbable ceramic supplemented with I.M. fixation and reported a 50% success rate. Hulbert and Kalwitter[30] bridged similar size gaps in dogs using inert porous ceramic. Three months after implantation, there was no radiographical evidence of osseous union at the ceramic bone interfaces. A histological evaluation confirmed this impression. Stanitski and Mooney[31] working with vitreous carbon, replaced a 2.5 cm. gap in a canine femur with the material and supplementary I.M. fixation. All implants failed to maintain to skeletal stability after implantation for less than 3 months.

Piotrowski, et al[32], replaced segments of femora in rats with an impervious glass ceramic material developed by Hench, et al[33]. After 28 weeks of implantation, 15 of the 16 animals showed nonunions which the authors attributed to insufficient immobilization.

It is obvious that the replacement of a segmental bone defect is a complex and multifaceted problem. It must be approached with attention to the technical, mechanical and biological conditions which exist, if one is to be successful in the application of a biomaterial used in this context.

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V. LONG BONE REPLACEMENT SEGMENTS - TECHNICAL DESCRIPTION

Four major type of segmental replacement devices have been designed for implantation in baboons encompassing those areas of the skeleton most frequently involved by the conditions previously stated. These are segmental diaphyseal replacements for the femur, tibia and humerus and a segmental replacement for the distal femur including the knee joint.

A. Femoral Segmental Replacement (see Figure 1)

This implant consists of a central section, 3 inches in length made of titanium fiber metal sintered to a hollow central cylinder of titanium alloy. The sintered fiber metal coating measures 1/8 inch in breadth. Semicircular

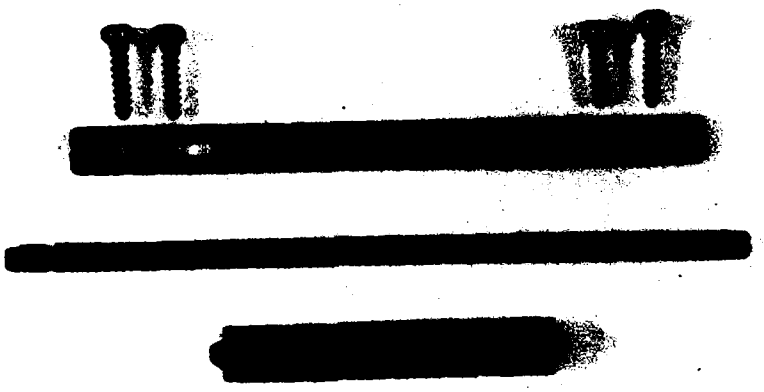


Figure 1 - Prosthesis assembly for femoral segment replacement

screws - top
plate
medullary nail
femoral segment - bottom

flanges are created at both ends of the segment to help provide rotatory stability and maintain alignment of the proximal and distal bony fragments. Fixation is provided by an intramedullary rod made of titanium alloy, 6 1/2 inches in length and coated with a thin sheet of porous fiber metal. The rod fits into the central hollow cylinder of the segment itself, as illustrated. Additional fixation is provided by a semitubular compression plate measuring 6 inches x 7/16 of an inch x 1/16 of an inch, which is affixed to the lateral aspect of the femoral shaft after compression of the intermediary segment.

B. Tibial Segmental Replacement

The tibial skeletal replacement components are essentially a scaled down version of those previously described. The central segment is identical with that of the femoral replacement with the exception that the length is reduced to 2 1/2 inches. The intramedullary rod is similarly scaled down to a length of 5 3/4 inches. The compression plate that is used on the lateral aspect of the tibial shaft after intramedullary fixation is 5 3/8 inches x 7/16 inches and is flat, rather than semitubular. Fixation of the plate is accomplished by 2.70 - 3.5 mm. diameter screws.

C. Humeral Skeletal Replacement

This prosthetic implant consisted of a trapezoidal shaped central section 2 inches in length, sintered to a central core of high strength titanium alloy 1/4 inch in diameter. This central core projects 1 inch and 1/2 inch from the proximal and distal aspects of the central sleeve, respectively, and is designed to fit the intramedullary cavity of the humerus. These projections are coated with fiber metal to obtain external diameter of 7/16 inch approximately and 3/8" distally. Supplemental fixation is supplied

by a specially contoured semitubular compression plate fixed anteriorly to the humerus. At the present time, this implant has been placed only in cadavers pending further modifications.

D. Distal Femur and Knee Segmental Replacement (see Figure 2)

Present segmental replacement designed for the purpose of replacing the distal femur and knee joint has undergone numerous modifications during the past year. The present model is the third prototype which has been developed. It consists of a proximal 4 inches long intramedullary rod made of high strength titanium alloy and coated with a thin sleeve of fiber metal. The actual segmental replacement allows for resection of the distal 3 inches of the femur and consists of a proximal 1 inch long fiber metal sleeve attached to the femoral component of the prosthetic knee joint. Bearing surfaces for the prosthetic knee are two cylinders, 1 inch in diameter and 1/4 inch wide. These are coated with a 1/16 inch tract of UHMW polyethylene-graphite. The tibial portion of the knee joint mates with the femoral component and has flexion and extension stops to allow for 120° of motion. Fixation of the tibial component is accomplished by methylmethacrylate while fixation of the femoral segment is accomplished by the addition of an angled semitubular plate which will allow for the compression of the fiber metal sleeve.

VI. SURGICAL PROCEDURE FOR SEGMENTAL REPLACEMENTS OF THE TIBIA

The components of the tibial segment prosthesis and the drill guide to locate the segment and shape the ends of the fragments are shown in Figure 3.

Baboons were placed in the supine position and the left lower extremity was shaved and prepped from the groin to the ankle. The leg was positioned in such a manner that the hip and the knee were flexed approximately 90°.

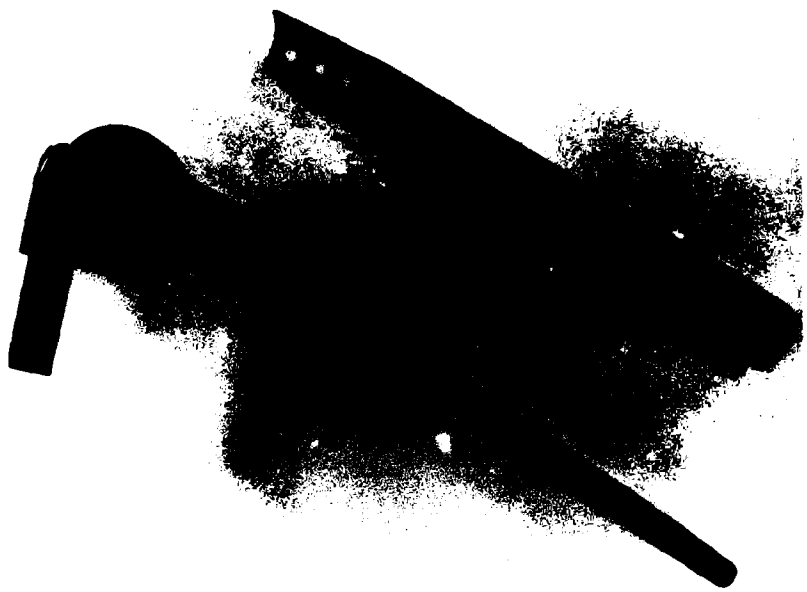


Figure 2 - Distal femur and knee segmental replacement.

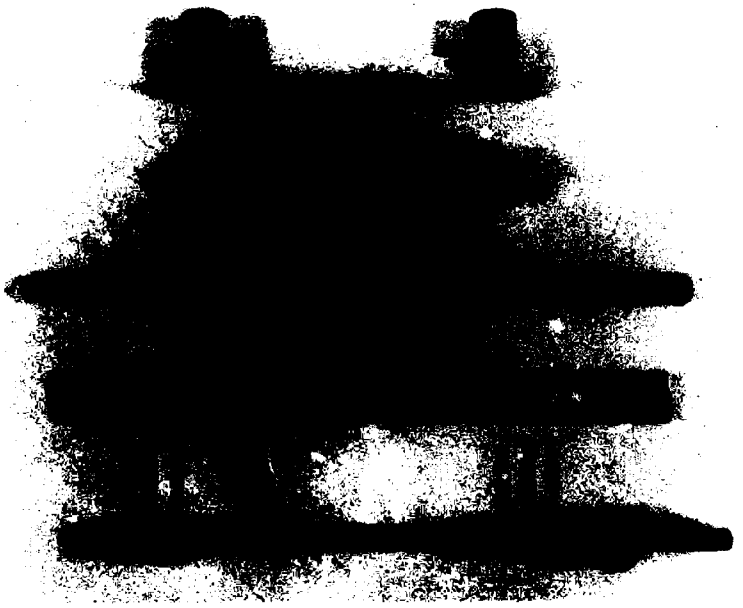


Figure 3 - Components of the tibial segment prosthesis and related tools for clinical implantation

drill guide - upper
tibial segment prosthesis
medullary nail
plate
compression device - lower

The leg was then draped in the standard faishion using a free-leg drape. An incision was made over the anterior medial subcutaneous border of the tibia, extending from the lower pole of the patella to just proximal to the ankle. The subcutaneous tissues were then incised in the line of the incision down to the periosteum. Next, the entire diaphysis of the tibia was extra-periosteally dissected from the surrounding musculature and hemostasis was obtained. At this point a specially designed drill guide was placed on the medial surface of the mid-shaft of the tibia and held in place with Verbrugge clamps. Two 1/4 inch holes were then drilled in the tibia and the guide was removed. Using an oscillating Stryker saw the tibia was then osteotomized in a plane perpendicular to its axis at the level of the proximal and distal drill holes. This portion of bone was then removed en bloc after dissecting away its posterior musculature attachments.

Attention was then directed to the tibial tubercle and insertion of the patellar ligament. The ligament was incised in a longitudinal fashion to expose the anterior surface of the tibial tubercle. A 1/4 inch diameter drill hole was then made in the tubercle, and the drill was directed obliquely down the medullary canal of the proximal fragment. Likewise, the medullary canal of the distal fragment was also reamed to a 1/4 inch diameter to accommodate the intramedullary rod. A trial reduction with the segmental replacement in place was attempted to insure the best contact at all points. Appropriate revision of the fragments was then done after trial reduction of placement did not appear to be well seated at both ends. Next, the fibula was osteotomized in an oblique fashion in its proximal one-third to prevent distraction of the fragments. The fiber metal segment was then placed in the appropriate defect and the distal fragment just proximal to the ankle. A specially designed plate to prevent rotation of the fragment was then clamped in place over the

lateral aspect of the tibia and drill holes were made in the proximal and distal fragments. The holes were then tapped and the appropriate size cortical screws were inserted. Care was taken not to strip the periosteum under the plate. Following this the wound was copiously irrigated with normal saline and hemostasis was obtained. The wound was then closed in the standard fashion with the exception of the distal portions of the extensor halucis longus and extensor digitorum longus which were mobilized anterio-medially to cover the fiber metal segment distally as at this portion the fiber metal was observed to be lying directly underneath the skin.

No post-operative immobilization was used and both animals received prophylactic antibiotics for a period of five days.

Complications encountered in the first operative procedure were: (1) the medullary canal of both the proximal and distal fragments was too large and hence it was impossible to obtain intimate contact with the fiber metal intramedullary rod. This in turn decreased the stability of the replacement segment; (2) although the medullary canal was wide, the cortex of the distal fragment was relatively thin being approximately 4 mm. in thickness. Since 4.5 mm. screws were used to fasten the plate to the bone and so doing the posterior cortex of the distal fragment was accommodated so much so that the screws had to be replaced with the standard bolts to obtain a fairly rigid fixation. This complication was thought to be due to a combination of factors including the thin cortex, the relatively large size of the screws, the oblique manner in which the screws had to be inserted to avoid the central solid core of the medullary rod and lastly, the proximity of the screw holes to the ends of the segmental defect; (3) the original drill guide was slightly undersized so the segment of bone removed was approximately 0.2 mm. smaller than the fiber metal replacement. This was done because it was believed that there would be some compression and hence more rigidity of replacement segment

when it was placed in the under sized defect. However, it was found at the first operation that the increased length of the replacement caused anterior angulation of both the proximal and distal fragments secondary to the pull of the gastrox and solius muscles, giving poor bone-metal contact at these points.

These complications were avoided in the second operation by: (1) choosing a baboon with a small medullary canal as measured on X-ray; changing the location of the screw holes on the plate so that they were at least 1 cm. away from the defect; decreasing the size of the cortical screws to 2.8 mm. making the defect slightly oversized and also osteotomizing the fibula to delete any possible distracting forces or angulating forces.

The only complication in the second operation was that the baboon had not as of yet reached maturity and hence had an underdeveloped tibial tubercle. Also there was less anterior convexity of the tibia than was normally present in most baboons. This fact made it almost impossible to drill a hole through the tibial tubercle without fracturing off a portion of the posterior cortex of the distal aspect of the proximal fragment. Despite this complication, the replacement was much more stable than after the first operation and with appropriate attention to pre-op X-rays this second complication can be easily eliminated.

VII. LONG BONE REPLACEMENT SEGMENTS - EXPERIMENTS

A. Femoral Segments

At the present time, femoral segmental replacements have been performed in ten adult baboons. Of these ten replacements, eight were done using the original technique and two were done with the new surgical technique and the addition of supplementary fixation by means of a compression plate. Of these animals, five have presently been sacrificed for histological study.

B. Tibial Segments

A total of seven tibial segmental replacements have been performed. Of these, two were done with a standard plate, without any compression being applied to the intermediary segment. Three animals were done with the addition of a compression plate and the remaining two animals had both a compression plate and a bone graft. None of these animals have been sacrificed for histological study at the present time.

Results

Clinically, all the animals which received either a femoral segmental replacement or a tibial segmental replacement, regained complete return of function of the operated limb. At the present time, none has exhibited any evidence of gait disturbance or deformity during the period of implantation.

All the tibial segmental replacements have been in place for less than six months. Preliminary evaluations show no loosening or migration of the prosthesis or loss of skeletal continuity. One animal which had both, a compression plating and bone grafting appears to have bony union at both the proximal and distal junctions and some reconstitution of the diaphysis, after six months of implantation. Since this animal had by far the best roentgenographic appearance of all those animals implanted, it was decided that all future segments will be supplemented by the addition of cortical cancellous bone grafts (see Figures 4 and 5).

The animals with femoral replacements which were sacrificed for histological evaluation, were composed of two three-month animals; one five-month animal; one eight-month animal and one animal which had the implant in place for one year. Histologically, only one bony-prosthetic interface showed bony ingrowth to a depth of approximately 5 mm. The

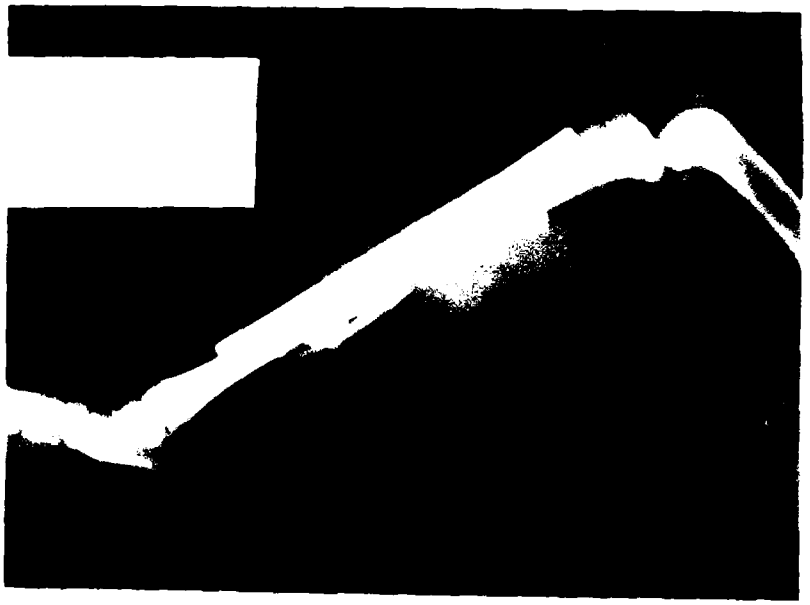


Figure 4 - Immediate post operative X-ray of a tibial segmental replacement supplemented with bone graft.

Figure 5 - Six-month post operative X-ray of a tibial segmental replacement showing apparent union at proximal and distal interfaces and some reconstruction of diaphysis.

remaining segments were all encapsulated with a fibrous tissue sheath, although the majority showed some peripheral bony ingrowth around the segment itself, encompassing 30-40% of the circumference. All segments evaluated showed complete and thorough infiltration of bone in the fiber metal coating about the solid intramedullary rod. All these five animals were in the initial group of segmental implants when numerous technical difficulties were encountered in the actual surgical implantation of the segments. Only one of these five animals had what was considered to be a proper placement of all component parts or did not require reoperation. This animal was sacrificed after only three months.

Since these original animals, the technique has become more sophisticated so that intimate contact between the intermediary segment and the proximal and distal bony fragments can be obtained readily, at the time of surgery. This is apparently very important, as previous experiments have demonstrated that this contact is necessary if one is to develop bony ingrowth rather than fibrous tissue.

Three of the remaining femoral segments appear to be completely infiltrated with bone and the entire femur reconstituted under radiological evaluation. In these animals, the segment has been in place for more than one year (see Figure 6).

The remaining two animals have had the implants in place too short a time for any radiologic assessment to be made.

C. New Techniques

To insure a more rapid regeneration of the excised fragment of the bone and a more complete incorporation of the prosthetic device into the skeletal structure of the host, two new techniques have been designed. The first technique involves the adding of compression to the surgical procedure (see

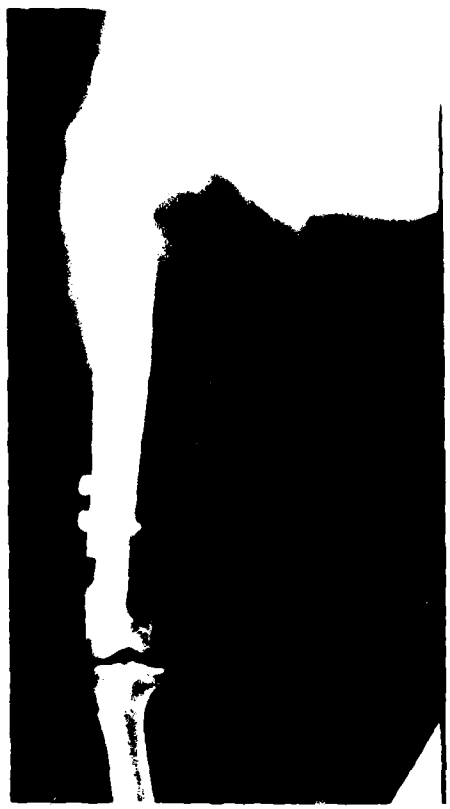


Figure 6 - Fifteen-month post operative X-ray of femoral segmental replacement showing apparent reconstruction of entire diaphysis.

Figure 3 for compression device). This accomplishes a significant improvement in the rigidity of the fixation at the time of surgery and insures a better match at the prosthesis-bone interface. This is achieved by designing the molded fiber components so that they crush slightly under the force of the actual compression device. This exploits one of the major advantages of this type of porous material, namely, that it is capable of sustaining plastic strain.

The second modification involves the addition of bone grafts placed in the periphery of the intermediary prosthetic segment. The addition of bone grafts in no way changes the basic premise of this investigation. The amount of bone used is relatively small and in the two cases in which this has been performed, it appears to accelerate significantly the rate at which union has occurred across the prosthetic segment. Evaluation of these two techniques will be performed in two groups of six animals each, where replacement of a segment of the femur and a segment of the tibia will be performed, respectively. Evaluation will involve sacrifice and recovery timed at three months, six months, one year and two years. Histological evaluation of the reconstructed segments will be performed using the techniques described above.

VIII. RADIOLOGICAL AND HISTOLOGICAL RESULTS

A. FEMORAL SEGMENTAL PROSTHETIC REPLACEMENT

Review of the results in the first in vivo implants in the baboon.

Ten adult baboons have been used in this study. Different surgical techniques were tested in an attempt to determine the relative advantage of each method. The animals have been followed radiographically and sacrificed according to a determined schedule.

This report summarizes the radiological evaluation of all implanted animals and the histological data available from six sacrificed animals.

(a) RADIOLOGICAL STUDIES

The radiological status of the implant was evaluated from two different points of view:

Callus Formation - represents evidence of active callus growth around the fiber metal segment.

Contact - represents close continuity between the implant and adjacent bone, being ideal when no radiolucent line is observed between bone and implant.

Contact was graded from 0 to 4, according to the extent of the

bone implant contact. The grading system was as follows:

0 - No contact

1 - Contact in one rod

2 - One rod plus one interface

3 - Both rods and one interface

4 - Both rods abd unterfaces

Rod refers to the intramedullary rod above and below the segment and interface represents the area of contact between the ends of the prosthetic segment and the bony proximal and distal segments. The ingrowth of bone in the rods and interface probably represents, primarily endosteal bone formation.

(b) HISTOLOGICAL STUDIES (See Tables I and II)

After sacrificing the animals the femora containing the segmental implants were fixed in 10% buffered formalin and studied radiographically to determine the different levels for the initial sections. RP-M2 Kodak contact film was used for this purpose.

The specimens were then divided in blocks and were embedded in Methylmethacrylate using a diamond wheel microtome; transverse, axial and oblique sections were cut from the most representative areas. The average thickness was 200 - 300 microns. Subsequently the specimens were stained with acid fuchsin and mounted on the slides.

Thinner sections were produced using petrographic techniques. Coarse, fine grinding and rough polishing was accomplished with 240, 320 and 400 grit SiC abrasive, while final polishing employed a

Femoral Implants

TABLE I - ANIMALS SACRIFICED

SURGICAL PROCEDURE	Sacrificed After	Immediate Post-Surgery Stability	X-RAY FOLLOW UP 3m	6m	12m	18m	Callus Present at	HISTOLOGY EVALUATION SECTIONS FROM Proximal Rod	Segment S_1	Sections* S_2	S_3	Distal Rod	** I_1	* I_2
Subperiosteal Implant No Compression No Bone Graft														
1687	4 mo	Acceptable	+1	+1	+1	+1	3 mo	+4	--	+1	--	0	+1	--
899	5 mo	Poor	+1	+1	+1	+1	3 mo	0	+1	+1	+3	+3	0	--
1163	5 mo	Very Poor≠												
628	8 mo	Poor	+1	+1	+1	+1	3 mo	+3	0	0	--	+1	+1	0
1069	12 mo	Poor	+1	+1	+1	+1	1 mo	0	0	+1	--	+4	--	0
347	14 mo	Good	+3	+4	+4	+4	3mo	+3	+4	--	--	+4	+2	+2

* S_1, S_2, S_3, = Different sections at different levels of the segment

** I_1, I_2, = Proximal and distal interfaces

≠ No rod was used

FEMORAL IMPLANTS

TABLE II - A N I M A L S A L I V E

SURGICAL PROCEDURE	SACRIFICE TIME	IMMEDIATE Post-Surgery Stability	X-RAY FOLLOW UP 3 mo.	6 mo.	12 mo.	18 mo.	Callus Present
Subperiostel No Compression No Graft							
638	24 mo.	Acceptable	+2	+2	+2	+4	1 mo.
617	24 mo.	Poor	+1	+1	+2		3 mo.
Extraperiosteal Compression Plate No Graft							
1002	12 mo.	Good	+2	+2	+2		1 mo.
Extraperiosteal No Compression No Graft							
924	24 mo.	Acceptable	+2	+1	+2		3 mo.

Syntron vibratory polisher with slurries of fine SiC or diamond particles. Sections as thin as 30 microns were obtained.

A measuring Nikon eyepiece and a superimposed radial grid was used to measure the depth and perimeter of bone ingrowth with an approximation of ±5 microns. The inner perimeter of the intramedullary rod and the tubular inner part of the segment were taken as references. The average bone ingrowth was calculated in relation to the average section of segment and rod.

Bone ingrowth was graded from 0 to +4, corresponding respectively to perimeters of: 0, 90, 180 and 360 degrees with bone completely embedding the implant.

(c) RESULTS

Histological study of the implants from the first five animals sacrificed showed very irregular bone ingrowth. The picture seen in these animals reveals the initial struggle to develop a suitable technique to immobilize the system bone-segment-rod.

After overcoming this initial difficulty the animal 347 was implanted. The study of these sections revealed by its histological appearance complete bone ingrowth to the inner surface of the intramedullary rod as well as the segment. This feature is constant around the entire perimeter. This complete penetration of the implant by bone at all different levels was the result of intimate contact and rigid immobilization.

The bone seen between the fiber metal is trabecular in nature. The collagen fibrils appear to be highly structuralized in ordered layers corresponding to the lamellar bone tissue pattern. Osteocyte lacunae are abundant in the growing trabeculae (Figures 7 to 13).

The radiological picture of bone ingrowth in the implant is very difficult to assess. The absence of a radiolucent area being the best criteria for bony union (Figures 14 and 15).

In summary, the segmental fiber metal femoral prostheses can be readily penetrated by bone ingrowth and solidly fixed to the distal and proximal femoral segments, provided that adequate surgical technique is used. A new series of animals is to be operated using compression alone and compression with autologous bone grafts to evaluate the effect of these variables on healing.

B. TIBIAL SEGMENTAL REPLACEMENT

An *in vivo* implantation study is currently in progress. Ten adult baboons have been implanted following four different surgical techniques. None of the animals have been sacrificed at present, except one animal suffering from severe surgical infection. No other data than radiographic follow up is available at present.

According to the results from the femoral implants study there seems to exist some correlation with the histological and radiographic picture, the presence of a radiolucent area adjacent to the implant appears to indicate no bone ingrowth. It is important to point to two facts which are observed frequently. Many implants

Figure 7:

Macrophotograph (X8), a sagital section of the segment and intramedullary rod at the level of the proximal interface. Notice bone ingrowth across the interface.

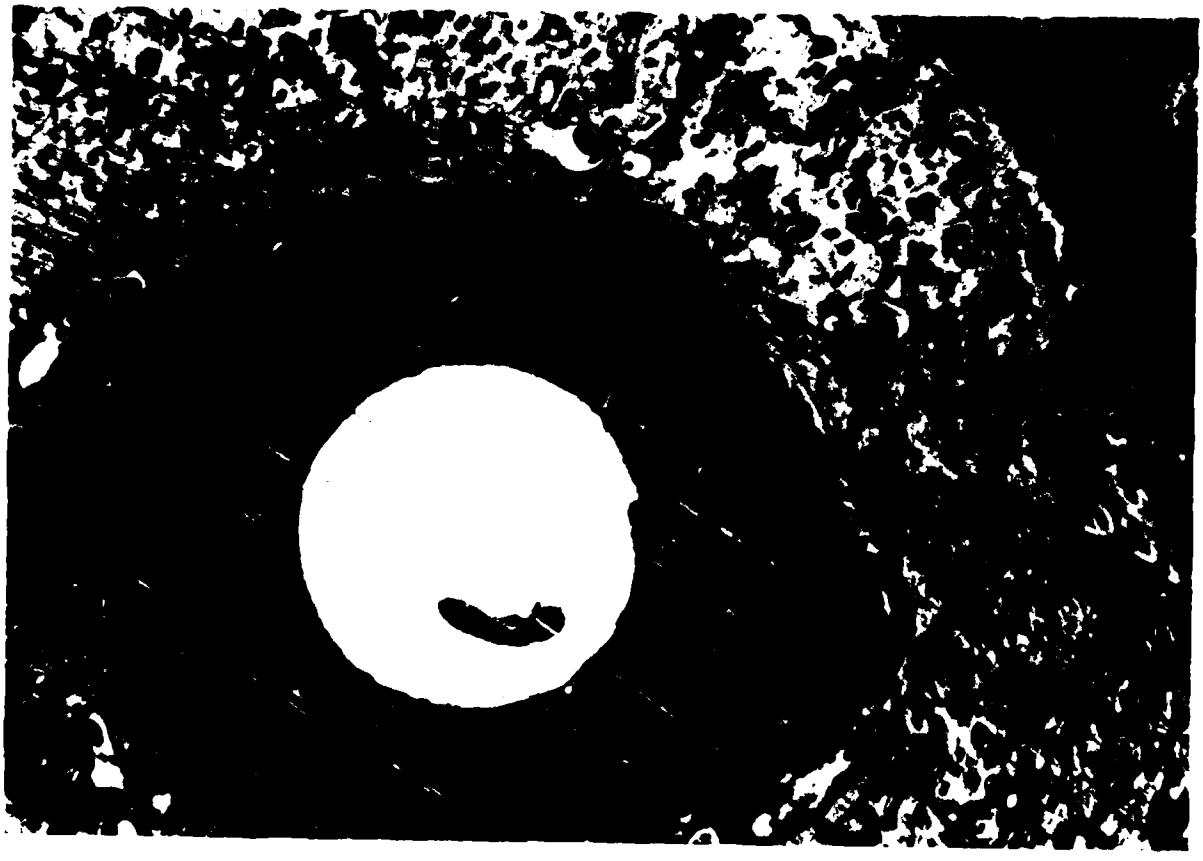


Figure 8:

Macrophotograph (X16), of the proximal intramedullary rod illustrating complete bone ingrowth to the inner surface.

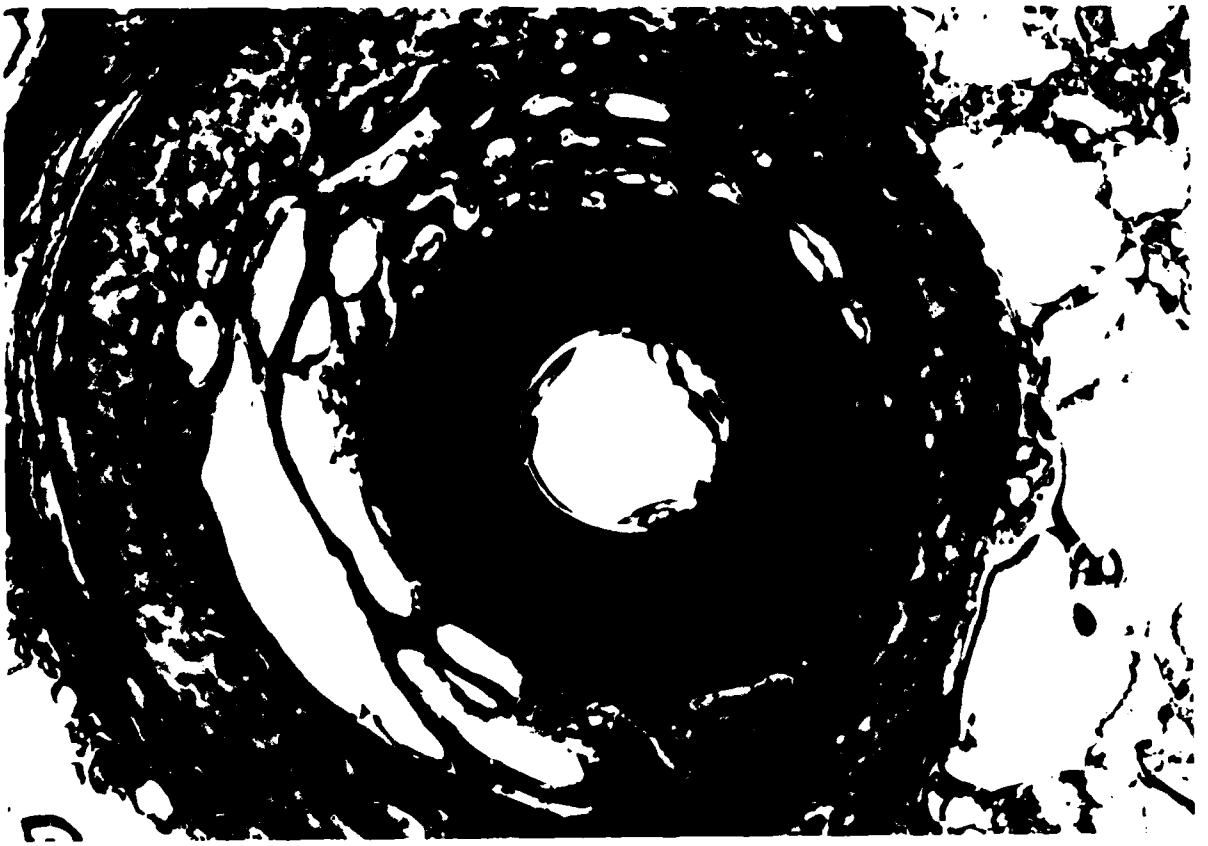


Figure 9:

Macrophotograph (X10), of the rod in the intramedullary canal. Bone has grown around the implant and penetrated in between the metal fibers to the inner surface.

Figure 10:

Microphotograph (X125), illustrating undecalcified ground section 40 microns of bone growing in between the fibers of the proximal interface.

Figure 11:

Microphotograph (X125), Bone ingrowth in the segment. The lower right hand corner illustrates the metal tube inside the segment demonstrating complete penetration. Notice the ordered lamellar pattern of the bone and the Haversian-sytem-like figure in the trabeculae.

Figure 12:

Microphotograph (X400) illustrating the intimate contact of the ingrowing bone with the fiber metal.

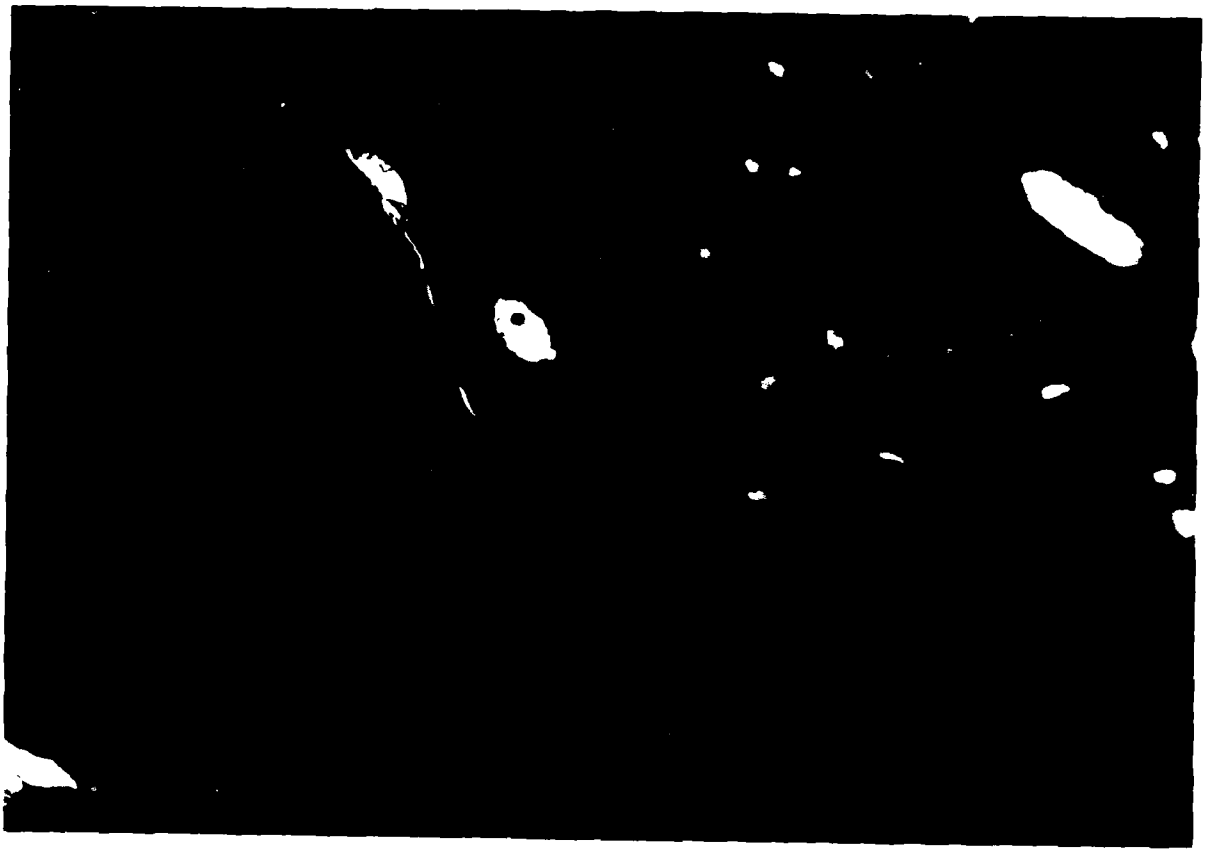


Figure 13:

Microphotograph (X312), illustrating the intimate contact of the ingrowing bone with the metal tube in the segment.

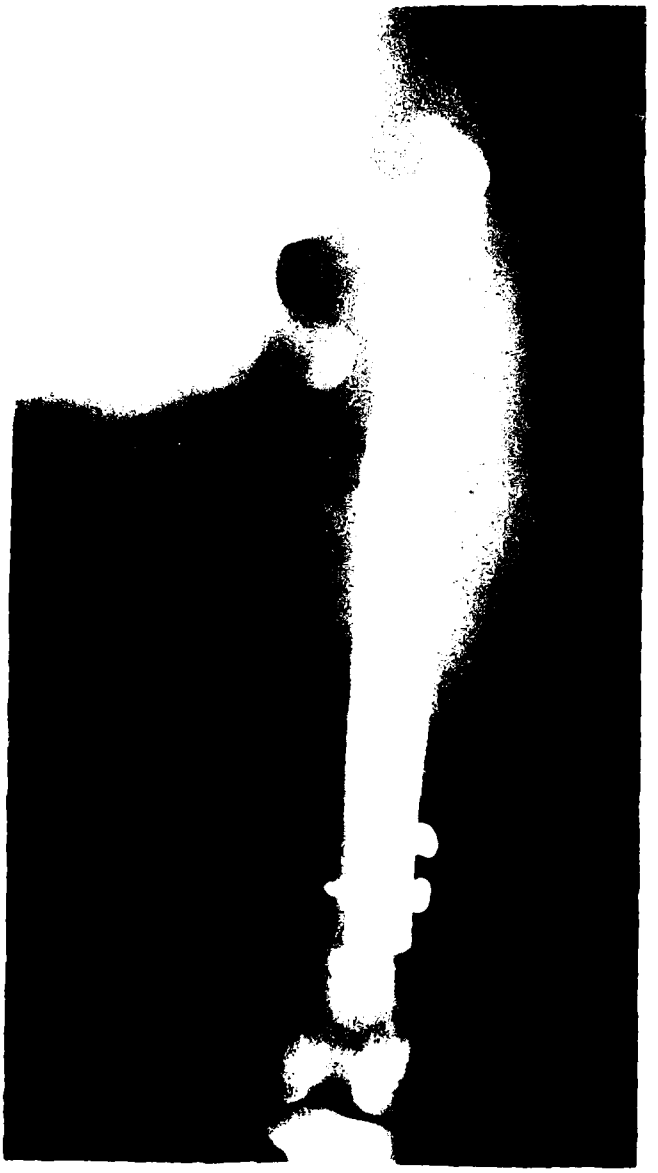


Figure 14:

AP view of femoral segmental replacement, 14 months after surgery. The prosthesis appears in good position and no radiolucent line is seen in between the bone and the implant.

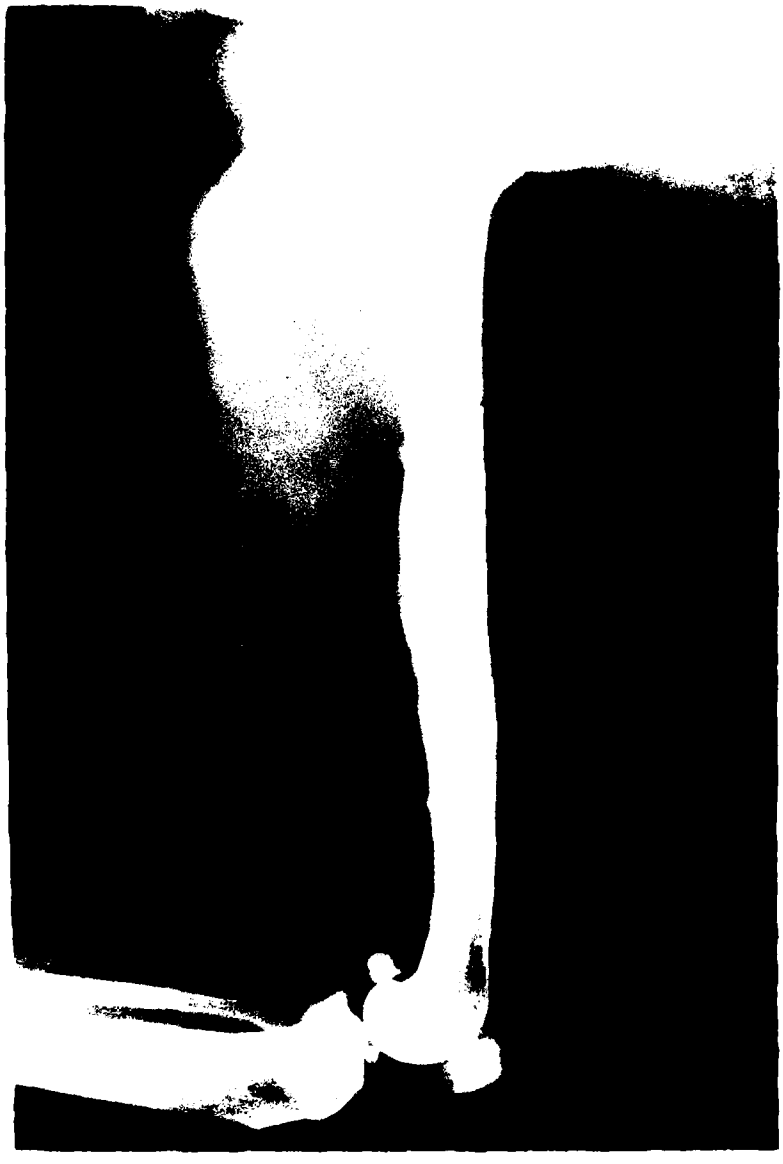


Figure 15:

Lateral view of the femur shown in Figure 8. Complete reconstitution of the diaphysis by bone ingrowth into the implant is seen.

in close contact with the bone, immediately after surgery develop some degree of bone reabsorption mainly at the level of the interfaces and in many cases this radiolucent area is obliterated after some time. The presence of this radiolucent line does not exclude further penetration by bone. If the stability of the implant is acceptable these areas tend to slowly obliterate as bone growth progresses around the implant.

The radiographic follow up has been tabulated comparing the different surgical techniques and immediate post surgical results (Table III). Close contact of the proximal and distal rod (R_1 and R_2) with the bone as well as close contact in the interfaces (I_1,I_2) has been tabulated at different times after implantation. Callus (C) presence around the segment has also been entered in the table.

Many of the tibial implants show a radiographic picture compatible with a solid bone fixation, especially where compression plate and bone graft around the implant were used. Most probably this picture will correspond to bone ingrowth in between the metal fibers (Figure 16).

C. HUMERAL SEGMENTAL IMPLANT

The intial design has been changed after trial on an isolated humerus of baboon and on a cadaver. The special curvature and torsion of this bone, with the irregular shape of the medullary canal were the initial obstacle to obtaining adequate stability of the implant after surgery even though a stabilizing compression plate

TABLE III - T I B I A L I M P L A N T S

TIBIA SURGICAL PROCEDURE	Will Be Sacrificed at Months	Immediate Post-Surgery Stability	RADIOGRAPHIC FOLLOW UP 1 mo.	 3 mo.	 6 mo.	 1 yr.	Callus at Months
Extraperiosteal No Compression No Bone Graft							
617	18	Poor	R_1R_2	$R_1R_2I_2$	$R_1R_2I_2$	$R_1R_2I_2$	
1640	12	Poor	$R_1R_2\frac{1}{2}I_2$	$R_1R_2\frac{1}{2}I_2$	$R_1R_2I_2$	$R_1R_2\frac{1}{2}I_1I_2$	
1642*							
No Compression Bone Graft							
1645	18	Adequate	$R_1R_2I_1$	$R_1R_2I_1$	$R_1R_2I_1\frac{1}{2}I_2$		6
Compression No Bone Graft							
1646	18	Adequate	$R_1R_2\frac{1}{2}I_1$	$R_1R_2\frac{1}{2}I_1I_2$	$R_1R_2I_1$		1
1644	12	Adequate	$\frac{1}{2}I_2$	$R_1R_2I_2$	$R_1R_2\frac{1}{2}I_2$		
Compression Bone Graft							
1648	12	Good	$R_1R_2I_1I_2$	R_1R_2			3
2179	18	Good	$R_1R_2I_1I_2$	R_1I_1			3
2061	12	Adequate	$R_1R_2\frac{1}{2}I_1\frac{1}{2}I_2$	R_1I_1			3
2062	18	Adequate	$R_1R_2\frac{1}{2}I_1\frac{1}{2}I_2$	R_1I_1			

* This animal was sacrificed after 6 months because of surgical infection.

R_1: Close contact between bone and proximal segment of the rod.

R_2: Close contact between bone and distal segment of rod

I_1: Close contact at proximal interface

I_2: Close contact at distal interface

Figure 16:

Lateral view of a tibial segmental replacement 3 months after surgery. Compression plate and bone graft around the implant was used. The prosthesis appears adequately placed and bone graft viable. Incipient callus formation and bone ingrowth are evident in the lower interface.

was used. The new design has an intramedullary rod through the segment stabilizing it to the distal and proximal humeral portions. This change will make the design close to the tibial and femoral spacers.

The new design has been tested satisfactorily in cadavers. A series of baboons will be implanted with this device using compression plate and bone graft and compression plate alone.

IX. PRELIMINARY HISTOLOGICAL REPORT ON THE MP35N ALLOY ("MULTIPHASE")

The MP35N alloy is a very high strength and reputedly corrosion resistant new alloy having the nominal composition: 35% Co, 35% Ni, 20% Cr, 10% Mo. This report includes the histological data available from a group of 10 animals implanted with the test material, sacrificed at 3, 2 and 1 month in groups of two. The remaining animals in this series for testing the biocompatibility of MP35N have not been sacrificed at present.

The implants were cut from solid MP35N rod 1/8" in diameter. The length of each individual rod was 1/2" and the approximate weight was 1 gm. The control specimens were 316L stainless steel rods of the same dimenions. Prior to implantation surface preparation was obtained following the recommendations of the ASTM for metallic surgical implants. Method 2 was used as described in the Standards for Surgical Implants.

A. IMPLANTATION PROCEDURE

Inbred strain rabbits of similar weight were utilized in this study. The implantation was accomplished by placing three rods in the paravertebral muscle. Each rabbit received six implants in total, two 316 L controls and four MP 35 N rods. The anesthetic used was given parenterally. The surgical areas shaved and washed. The paravertebral implants were introduced through a posterior midline incision after dissecting the muscle. The femoral implants were introduced through a drill hole in the bone.

The implants were handled during surgery with Teflon coated instruments, standard aseptic surgical technique was used during the procedure.

B. HISTOLOGICAL PROCEDURE

After sacrificing the animals at scheduled times, the implants were removed "en bloc" with the surrounding tissue and immediately fixed in 10% buffered formalin. The samples containing the implants were carefully dissected to remove the rod with minimal trauma to the tissues.

The muscle specimens were embedded in parafin blocs and sectioned in a plane transverse to the long axis, stained with Hematoxilin-eosin and mounted.

The femoral implants were removed after sectioning the bone, the blocs were decalcified in Cal-Ex solution, embedded in parafin and stained in acid fuchsin after sectioning.

A Young microtome was used for bone and soft tissue; the average thickness of the sections was 6 microns.

The histological samples were studied to evaluate the reaction produced in the tissue. The fibrous membrane encapsulating the implant was measured at four different points with a Nikon measuring eyepiece. Areas of active cellular proliferation and conventional granuloma formation were recorded as well as the presence of pleomorphism and mitiotic figures. The presence of foreign body particles (corrosion particles of some authors), dominating type of fibrocyte and blood vessels in the membrane were all tabulated. This histologic study also included the area immediately adjacent to the membrane which was measured when it consisted of fatty degeneration tissue. Type of cellular proliferation, presence of giant cells, macrophages containing phagocyted particles and polymorphonuclear leukocytes in this area was tentatively given a quantitative value.

C. REACTION IN MUSCLE

In the one month samples, no granulomatous or gross proliferative reaction is observed in the membrane encapsulating the implant. The average thickness of this membrane is 12 microns, ranging from 5 - 30 microns. The contour is regular and occasional small foreign body particles are present in almost all specimens. No blood vessel proliferation is seen inside the membrane. Fibrocytes correspond to the more immature type.

Almost constantly, the surrounding tissue presents a mild degree of cellular infiltration with occasional macrophages containing phagocyted particles. Conventional foreign body giant cells were observed only in one slide. The area of fatty degeneration appears very irregular, ranging from 150 microns to 25 microns in thickness, with a mean of 69 microns. Degenerated muscle fibers and tissue debris are frequent in this zone.

ONE MONTH			TWO MONTHS			THREE MONTHS		
Specimen	Membrane	Control	Spec.	Mem.	Cont.	Spec.	Mem.	Cont.
28-3	5		26-1	15		24-1	5	
28-4	10		26-2	10		24-3	10	
28-5	10		26-5			24-4	30	
28-6	15		26-6	10		24-2		
28-1		20	26-4		20	24-5	2	0
28-2		20	26-4			24-6		15
29-2	30		27-1	15		25-2	10	
29-3	10		27-2	15		25-3	25	
29-4	5		27-3	25		25-4	20	
29-5	10		27-4	10		25-5	10	
29-1		10	27-6	30	30	25-1		25
29-6		60	27-5			25-6		12

The controls showed an average membrane thickness of 27 microns and the same type of reaction in the surrounding tissues. In one specimen a distinct area of cell proliferation is seen in the membrane and eosinophils are present in the nearby tissue.

In the two month specimens the average membrane thickness is 14 microns. The zone of fatty degeneration is also very irregular but less necrotic tissue is present. Foreign body particles are more

abundant and there is milder cellular reaction in the surrounding tissue. Essentially the infiltrate is constituted by the same type of cells present at one month.

In three months the average membrane is 16 microns. Fibrocytes are immature. In two specimens a mild proliferation is seen in one area of the fibrous membrane, however cells are distributed regularly and no pleomorphism or mitiotic figures are evident. Particles are a constant feature of all sections. The zone of fatty degeneration is very irregular and no signs of active necrosis are present. Cellular infiltrate in the muscle is minimal. In one specimen eosinophils are abundant.

D. REACTION IN BONE

The study of this tissue presents the problem of lacking an obvious proliferative cell reaction. The fibrous membrane is difficult to preserve during the sectioning of the blocs.

In general there is no appreciable osteolytic or osteoblastic reaction of the bone in close contact with the implant. After one month, the sample seems to be still floating freely in the marrow cavity. No organized cellular membrane is seen in any of these samples. Three months after implantation an encapsulating fibrous membrane 10 microns thick is observed rather constantly. Bone trabeculae around the implant are present in very few instances.

Control using 316 L presented exactly the same histological picture described above. In one slide the implant appears almost surrounded by bone trabeculae.

E. CONCLUSION

Because of the short implantation time, it is adventurous to draw general conclusions about the MP 35 N tissue tolerance. However, comparing the data available with the controls (316 L is believed to be a biologically low reacting material) the histological picture is encouraging. The membrane is thinner in MP 35 N than the controls and we expect this value to be lower in the six months specimens. At the present time the specimens fit in Group II of Laing classification, corresponding to materials giving little tissue reaction. We can extrapolate that from the histological point of view these preliminary results are promising and indicate a very acceptable degree of tolerance by living tissue.

X. IN VIVO CORROSION OF METALLIC PROSTHESIS MATERIALS

The degree of inertness of prostheses manufactured from reputedly corrosion resistant metals has not been well documented. The approaches have been from two directions. By one approach the hard tissue surrounding the implant is examined by histological procedures for toxic or other adverse responses. The assumption is made that if the implant has corroded, the corrosion products whatever their concentration and identities have been responsible for the histological observations.

By another approach one seeks to identify the migration of metallic ions into the surrounding hard tissue and characterize these migrations (presumably derivative from corrosion processes) in terms of concentration-distance profiles. The electron microprobe analyser is peculiarly suited to this type of investigation. It registers accurate analyses in a sample area about one micron (micrometer) in diameter.

A program of implantation of solid cylinders of specimen materials in the femurs of dogs has been in progress during the past 18 months. Each dog has implants of the following materials:

stainless steel, 316L

cobalt-chromium alloy (wrought Vitallium)

unalloyed titanium

MP35N (Multiphase) Co-Ni-Cr-Mo alloy

Some of these dogs have been sacrificed and the implants recovered with the surrounding hard tissue intact.

The microprobe analyses were performed at the American Dental Association by Mr. John Lenke under the supervision of Dr. W. Lyons. The instrument itself is a Cambridge Microscan 5 with two linear focussing spectrometers which permits simultaneous analysis of two elements.

In this task a major problem is identifying the location of the bone/metal interface. This has been accomplished by the use of a calcium atom scan. Since calcium does not exist in the metal nor can it penetrate or diffuse as the result of implantation, the interface is located where the calcium concentration drops abruptly to very small numbers i.e. from > 10% to < 1%.

Tables IV, V and VI summarize the results for three specimens. The analyses are reported in one micrometer (micron) steps or intervals. The calcium scans indicate that the instrument can locate the bone/metal interface in a zone of about 3 micrometers thick. It does not seem to be more definitive than that. The existence of metal ions of all species outside the body of the metal implant is indicated only in this same region of uncertainty. So far one must say that at the very most, corrosion imparts ions or corrosion products to a band of surrounding bone no more than three micrometers thick and the band is probably even less because the true interface position is in this same region.

XI. HAZARD OF COUPLE CORROSION AMONG PROSTHETIC METALS

Metals must meet three basic requirements to be acceptable for use in prosthesis. They must possess high strength, sometimes high wear resistance, and high corrosion resistance. The high wear and corrosion resistance is not necessary from a standpoint of structural integrity, but because of tissue inflammation caused by a relatively small amount of wear particles and corrosion products, the wear and corrosion rates must be very low. While it is possible for a metal to possess two of these three requirements, all three are rarely found in a single metal. It would be desireable to combine

SOLID VITALLIUM IMPLANT
ONE YEAR

Point	Wt%Ca	Wt%Cr	Wt%Co	Wt%Ni
15	27.1	N.D.	N.D.	N.D.
16	28.4	N.D.	N.D.	N.D.
17	30.0	N.D.	N.D.	N.D.
18	28.5	N.D.	N.D.	N.D.
19	27.9	N.D.	0.1	N.D.
20	28.2	N.D.	N.D.	N.D.
21	26.0	0.3	0.2	N.D.
22	23.6	0.8	0.4	N.D.
23	13.3	1.8	1.2	0.1
24	5.4	3.1	2.9	0.4
25	3.0	4.5	5.7	0.9
26	1.6	6.2	8.9	1.3
27	1.2	8.3	13.7	1.9
28	0.5	13.7	19.3	3.1
29	N.D.	13.6	30.9	4.8
30	N.D.	11.0	34.9	5.6
31	0.4	8.4	34.5	6.0
32	N.D.	9.2	31.6	5.0
33	N.D.	10.7	25.9	4.0
34	0.3	11.8	22.4	3.9
35	0.5	11.0	24.4	4.0
36	0.6	9.6	26.5	4.4
37	0.7	10.6	25.0	4.0
38	0.5	12.5	23.0	3.5
39	0.5	14.1	23.6	3.9
40	0.6	13.5	30.6	4.8
41	0.8	12.8	30.8	5.4
42	1.0	12.6	30.2	5.4
43	0.8	11.8	30.5	4.9
44	0.8	16.4	30.3	5.0
45	0.5	20.9	31.9	5.4
46	0.5	22.0	33.5	5.1
47	N.D.	23.0	50.3	7.8
48	N.D.	23.0	54.9	8.5
49	N.D.	23.2	55.9	8.8
50	N.D.	22.9	57.4	8.9

N.D. - Not Detected

TABLE V

Summary of metal ion concentrations at one micron intervals near a bone/Vitallium interface.

SOLID 316 L IMPLANT
ONE YEAR

Point	Wt%Ca	Wt%Cr	Wt%Fe	Wt%Ni	Wt%Mn	Wt%Mo
10	28.5	N.D.	0.4	N.D.	N.D.	N.D.
11	29.1	N.D.	0.3	N.D.		
12	29.2	N.D.	0.2	N.D.		
13	28.8	N.D.	0.3	N.D.		
14	30.6	N.D.	0.2	N.D.		
15	30.6	N.D.	0.3	N.D.		
16	28.9	0.1	0.5	N.D.		
17	28.0	0.1	0.7	N.D.		
18	25.1	0.1	1.0	N.D.		
19	19.7	0.2	0.9	N.D.		
20	16.7	0.1	1.0	N.D.		
21	10.9	0.3	0.9	N.D.		
22	4.6	0.2	0.8	N.D.		
23	3.4	0.3	1.0	N.D.		
24	2.1	0.2	1.7	0.2		
25	1.5	0.2	3.3	0.4		
26	1.4	0.3	5.7	0.8		
27	0.9	0.6	12.0	1.7		
28	0.3	1.3	21.5	3.9		
29	N.D.	1.9	36.6	6.1		
30	N.D.	5.0	42.4	7.5		
31	N.D.	7.9	52.5	9.4		
32	0.4	10.4	62.6	11.3		
33	0.5	15.8	65.2	11.7		
34	0.3	16.7	64.9	11.8		
35	N.D.	16.6	64.6	11.7		
36	N.D.	16.7	65.5	12.1	N.D.	
37	N.D.	16.8	65.2	12.0	0.1	
38	N.D.	17.1	65.0	12.5	0.7	
39	N.D.	16.8	65.0	12.5	1.0	
40	N.D.	17.4	66.3	11.9	1.1	N.D
41	N.D.	17.5	65.5	12.5	1.7	3.1
42	N.D.	17.0	64.9	12.0	1.9	2.3
43	N.D.	16.7	65.4	11.9	2.2	3.4
44	N.D.	16.8	65.1	12.3	2.1	1.5
45	N.D.	17.2	66.1	11.7	2.1	1.5

N.D. - Not Detected

TABLE V

Summary of metal ion concentration at one micron intervals near a bone/stainless steel 316L interface.

MULTIPHASE (MP 35_N)
SIX-MONTH

Point	Wt%Ca	Wt%Cr	Wt%Co	Wt%Ni	Wt%Mo
25	28.6	N.D.	0.1	N.D.	N.D.
26	28.9	N.D.	0.1	N.D.	
27	27.7	N.D.	0.1	N.D.	
28	28.5	N.D.	0.1	0.1	
29	28.0	N.D.	N.D.	N.D.	
30	27.6	N.D.	N.D.	N.D.	
31	26.4	N.D.	0.1	N.D.	
32	26.1	N.D.	N.D.	0.1	
33	26.9	N.D.	0.2	0.1	
34	25.9	0.1	0.1	0.2	
35	26.6	0.1	0.2	0.2	
36	25.6	0.2	0.5	0.4	
37	22.3	0.3	0.6	0.6	
38	15.7	0.4	0.7	0.7	
39	7.6	0.4	0.7	0.7	
40	3.8	0.6	0.9	0.8	
41	2.5	0.8	1.6	1.5	N.D.
42	1.7	1.3	2.8	2.9	0.6
43	1.5	2.4	6.5	6.9	N.D.
44	3.1	8.8	21.1	21.5	1.4
45	3.1	9.0	14.7	15.4	4.9
46	0.5	9.5	15.9	17.5	5.6
47	0.5	10.4	15.7	17.8	2.5
48	0.4	9.8	14.8	16.2	2.9
49	0.4	9.5	14.6	15.4	2.1
50	0.4	8.6	14.3	15.3	1.5
51	0.5	8.3	14.8	15.6	2.7
52	1.8	9.8	17.7	18.8	1.4
53	1.2	16.3	29.4	29.8	3.4
54	N.D.	19.1	34.0	33.9	8.7
55	N.D.	19.4	34.3	34.4	9.3
56	N.D.	19.4	34.4	33.7	8.7
57	N.D.	20.8	34.8	34.0	7.1
58	N.D.	19.8	35.0	35.1	11.3
59	N.D.	20.5	34.9	34.4	10.0
60	N.D.	20.3	34.5	34.0	11.1

N.D. - Not Detected

TABLE VI

Summary of metal ion concentrations at one micron intervals near a bone/multiphase alloy interface.

different metals in a manner such as to produce prosthesis possessing high strength, high corrosion resistance, and high wear resistance. Such metal combinations have been avoided because of a fear of galvanic corrosion.

Galvanic corrosion occurs when dissimilar metals come into electrical contact in an electrolytic fluid environment. The different electrochemical potentials of the metals give rise to an electric potential, or voltage, and current flow which causes the more anodic of the two metals to corrode at an accelerated rate. The fluids of the human body, from a galvanic corrosion standpoint, are essentially an aerated 1% saline solution at 37°C. This being an electrolytic solution could lead to galvanic corrosion in implants constructed of two dissimilar metals.

While there is sound theoretical and practical basis for the occurrence of galvanic corrosion, there may be cases with the coupling of high corrosion resistance metals, that galvanic corrosion will not occur. Corrosion resistant metals owe their high corrosion resistance to the presence of a passive film. This passive film is a thin oxide layer on the metal surface that protects the metal from chemical attack. Oxide films are generally nonconducting and should the electrical resistance of these passive films be high enough, it may be possible that electrical current will not be able to flow despite the existance of an electrical potential. Should this be the case, the passive film will prevent galvanic corrosion the same way insulation on two crossed wires prevents a short circuit.

To detect low corrosion rates of metals in electrical contact a new corrosion test was developed. This test used that highly developed diagnostic technique of metallography, where metal surfaces are highly polished to allow examination of the metal structure, to detect corrosion. Specimens took the form of right cylinders 1/2 to 1 1/2 inches in diameter and 1/2 to 1 inch in

height. A 3/16 inch hole is drilled through the center of the specimen along the cylinder axis. One of the end faces of the specimen is then metallographically polished to a surface that is mirror-like and scratch free up to 1,000x magnification under an optical microscope. This polished surface will easily show up any disturbance on the metal like a corrosion pit or film. The polished face is degreased with acetone, ethanol and then a distilled water rinse. To test a particular metal combination for galvanic corrosion, specimens of each of the two metals are joined with the two polished faces in contact by the use of a nylon bolt through the two center holes in the specimens, as shown in Figure 17. The nylon bolt is non-conducting and will not form other galvanic cells where it contacts the specimens or otherwise affect or distort the test results. This corrosion couple is then placed in a 1% NaCl solution that is open to the air and kept at a constant 37°C, that is, at body temperature. It is important that the container holding this test system is left open to the air so that oxygen can readily dissolve into the saline solution. Distilled water must continually be added to keep the fluid level constant in the container or evaporation would increase the NaCl concentration of the solution.

When the test is ended, typically after 100 days of exposure, the specimens are removed from the container, unbolted, rinsed and dried. The highly polished surface then enables the specimen to be microscopically examined for corrosion that would otherwise be obscurred by scratches and surface irregularities. This microscopic examination gives this test method a very high detectability. The maximum allowable corrosion rate in prostheses is about 0.01 mils per year; with a 1 inch diameter specimen in a 100-day test, the detectability limit of this test method is estimated to be 3×10^{-7} mils per year. It must be noted that this detectability limit figure

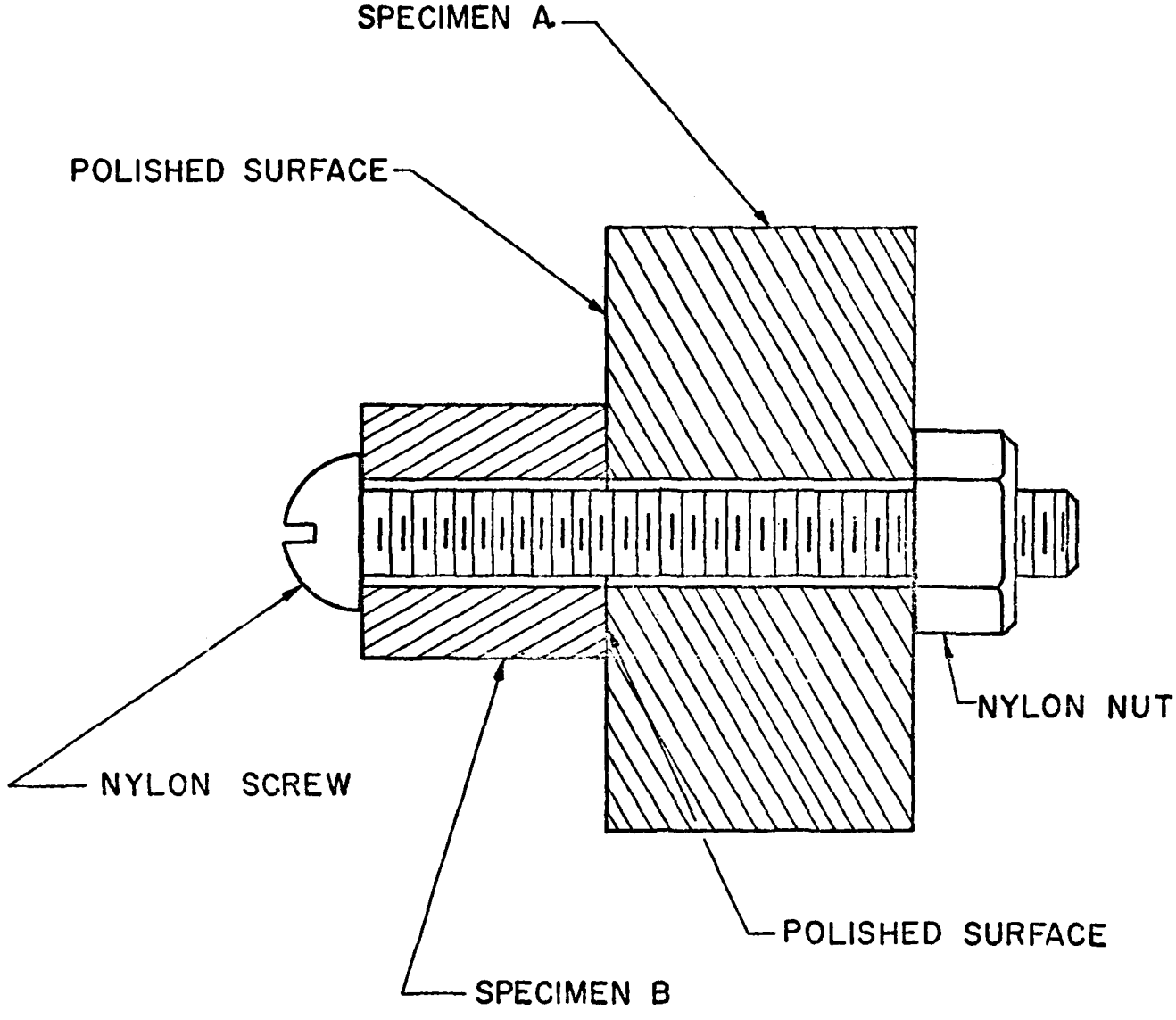


Fig. 17 - Diagram of the corrosion specimen assembly. Note that the assembly is totally immersed in the corrosion medium.

is an approximation and that this test method is more or less qualitative in terms of determining a corrosion rate.

The geometry of the interface of the two polished surfaces introduces another desirable feature of this test method, that of a crevice corrosion configuration. When an area in a corrosive fluid has a geometry that restricts fluid flow or diffusion, such as two facing metal surfaces, a pit, or a crevice, the oxygen concentration of the saline solution in an area becomes reduced. This reduction is due to oxygen consumption by the corrosion half-reaction: $[O] + H_2O + 2e^- \rightarrow 2(OH^-)$ and an inability to resupply the area with oxygen because of the geometrical restrictions. With two substantially different oxygen concentrations in the same corrosion system, namely inside and outside the crevice, a concentration cell is formed. Here the different oxygen concentrations leads to a electrochemical potential difference instead of a difference in the coupled materials. This potential difference makes the crevice area anodic so that increased corrosion or localized corrosion will occur in the crevice. Crevice corrosion problems exist in many prosthetic applications; the crevice created beneath the screwhead in a bone plate is but one example.

Thus the metallography corrosion test method is a high detectability test for both galvanic and crevice corrosion. For a sole crevice corrosion test, two specimens of the same material are merely used in the same corrosion couple.

The metals investigated were 316L stainless steel, cast vitallium, Ti-6Al-4V and multiphase. These metals where coupled to graphite, which being the most anodic material, should lead to the generation of the largest possible electrical potential. The corrosion couples were kept in the aerated saline solution for 100 days or until it was apparent that significant

corrosion had taken place. Corrosion of the 316L stainless steel was apparent after 10 days of exposure. The corrosion took the form of pits and a film of corrosion product that was especially heavy at the edge of the graphite-metal interface.

To determine the extent of the contribution of crevice corrosion in this; a crevice corrosion couple of two 316L stainless steel specimens was tested. Significant corrosion had again taken place in 10 days. The tufted region in the center was an area where severe anodic dissolution had taken place, removing quite a bit of metal, but no red corrosion product is seen because of the absence of oxygen deep within the crevice. The majority of corrosion product lies around the outside of the corrosion interface. The large amount of crevice corrosion led to the uncertainty that the porous nature of the graphite would result in the formation of small crevice corrosion sites at pores on the interface throughout the interface surface. To eliminate this possibility, the graphite pores were sealed by mounting the graphite in epoxy. A center nylon bolt could no longer by used, so the couple was held together on the outside by means of two polymethyl methacrylate strips and two nylon bolts. Significant corrosion was still formed in about ten days. It was concluded that 316L stainless steel was susceptable to galvanic corrosion in the presence of graphite and to crevice corrosion. The crevice nature of the corrosion couples caused 316L stainless steel to corrode coupled to any metal specimen.

Other metals tested were cast and wrought Vitallium, Ti-6% Al-4% V, and multiphase. These three metals showed little evidence of corrosion in contact with porous or sealed graphite, even after 100 days. There was the formation of a film on the outside of the interface and was heaviest at the interface edge. This film was observed on all specimens in tests lasting 40 days or more & appeared to have the same structure in all cases. Swabbing with a wet cotton applicator

would remove the film showing a polished undisturbed surface below. A scanning electron microscope study revealed the flecks that comprised the film to seem amorphous from their structural appearance, that they lie on the metal surface, not in it; and they are insulators that charge up under an electron beam. Corrosion products are generally a form of metal oxides that are semiconductors, not insulators, that would not charge up under the beam. These facts seem to indicate the film is not a corrosion product, but a precipitate formed from either impurities in the saline solution or impurties introduced into the saline solution from the atmosphere. Uncoupled samples of all of these specimens did form one or two small pits in 74 days.

An exception to this is a yellow film that formed on the interface interior between sealed graphite and Multiphase. While this film was composed of flecks as was the white film, the flecks were more rounded and being on the interior suggest that slight corrosion may have taken place rather than a precipitation of deposit formation.

Metal to metal combinations were now tested; Multiphase to cast Vitallium, cast Vitallium to Ti-6Al-4V, and Ti-6Al-4V to Multiphase. Aside from the formation of the above mentioned white film, the metals surfaces appeared undisturbed and uncorroded for the full 100 days. Crevice corrosion couples for 100 days also showed no signs of crevice corrosion. Cast Vitallium was also coupled to wrought Vitallium for 100 days, with no corrosion apparent.

In actual prosthetic application, the probability that the metal would be scratched at the same time or another is rather substantial. The protective passive film of these metals, being an oxide, is rather brittle and could be removed by wearing, or scratching the metal. It must be determined if the passive

film can reform in the corrosive environment especially in the oxygen depleted environment of a crevice, to maintain the corrosion resistance of the metal or if destruction of the passive film leaves the metal unprotected and highly susceptable to corrosion. A coupled corrosion scratch test was devised for this purpose. Specimens were indented a number of times with a diamond pyramid under a 20 kilogram load as used in a Vickers hardness test. The indentation causes adjacent material to uplift, forming a burr around the indentation. When the couple is assembled and the two specimens are twisted in opposite directions, each of the specimens is scratched by the burrs. This scratching removes the passive film without introducing any foreign material or otherwise disturbing or distorting the test and its results. Only a few scratches are formed so the high detectability of the test remains. The twisting can be done in such a fashion as to form scratches in only one half of the sample surface. This allows one to observe the corrosion behavior of the metals in the undisturbed state, with scratches, with heavy cold work (around the indentations), and with heavy cold work with a pit-type geometry, in the indentation itself.

This test was performed for the metal combinations of Multiphase and Ti-6Al-4V, Multiphase and cast Vitallium, cast Vitallium and wrought Vitallium, and cast Vitallium and Ti-6Al-4V. The scratch test was also performed with crevice corrosion couples for cast Vitallium, Multiphase, and Ti-6Al-4V. The corrosion couples were assembled and exposed to the corrosive environment for one week before the specimens were twisted to form the scratches. This was to allow time for the formation of an oxygen depleted zone in the crevice. The twisting was under the corrosive solution so the couple was never exposed to air in the meantime and the anaerobic condition of the interface was left undisturbed.

In all cases Ti-6Al-4V, wrought Vitallium and cast Vitallium showed no corrosion in the scratches. It did appear, however, that a corrosion film would form at some of the scratches in Multiphase when coupled to Ti-6Al-4V. This corrosion was not severe, did not lead to pitting and was seen in only some of the scratches. Corrosion was also apparent on some of the heavily deformed and sheared metal of the burrs by the indentations. Corrosion was also apparent on some but not all of the burrs by indentation on cast Vitallium when coupled to itself (a crevice corrosion couple) or to Ti-6Al-4V. When viewing possible corrosion by these burrs, one must take care not to confuse the heavily deformed or sheared surface of the burr to be corrosion. This is accomplished by using high magnification like 1000x so that one can see the flow lines on the burr or to determine that the metal surface actually rises as does a burr, and is not a depression formed by corrosion. This is done by focusing up to the burr center, rather than focusing down into it. The corrosion on the cast Vitallium appears as a film, similar to that on the multiphase scratches mentioned above, and does not give rise to severe corrosion or pit formation. In no cases was corrosion observed inside the indentations of the scratch test specimens.

Summary

Observation of a metallographically polished metal surface is a very sensitive indicator of the occurrence of corrosion and its severity. The conditions of the test are probably more severe than a normal *in vivo* environment because 316L stainless steel can be induced to demonstrate visible corrosion under crevice conditions in less than 10 days whereas screws and plates of this same material only rarely generate enough corrosion to elicit an inflammatory response.

Table VII summarizes the indications of corrosion of dissimilar materials in a crevice configuration. With the materials selected for the study there seems to be no indication that the coupling of unlike metals exacerbates the corrosion process. Apparently with metals possessing a refractory passive film, couple corrosion does not seem to occur. Crevice conditions do not induce accelerated corrosion except in the case of 316L stainless steel.

All metals seem likely to generate a very small amount of random pit corrosion. No metal is free of this possibility. The origin of these pits is likely to be microstructural heterogeneities related to their commercial processing.

Abrasion or scratching while immersed in the corrosion medium is expected to rupture the passive film and allow active corrosion unless the metal can reform the film. Titanium seems quite capable of doing this but Vitallium and Multiphase seem to show slight corrosion tendency. These results are summarized in Table VIII.

TABLE VII. SUMMARY OF TEST RESULTS

EFFECTS ON PRIMARY MATERIAL

TITANIUM ALLOY	MULTIPHASE	316L STAINLESS STEEL	CAST VITALLIUM
a few random pits after 74 days- polished surface preserved	a few random pits after 74 days- polished surface preserved	heavy pitting, staining and corrosion after 50 days	a few random pits after 74 days- polished surface preserved
no corrosion after 100 days	slight corrosion film in small area of sample after 100 days	heavy pitting, staining and corrosion after 10 days	no corrosion after 100 days
see crevice corrosion	no corrosion after 100 days	———	no corrosion after 100 days
no corrosion after 100 days	see crevice corrosion	heavy pitting, staining and anodic dissolution after 10 days	no corrosion after 100 days
———	no corrosion- polished surface stained by corrosion of 316L S. S.	see crevice corrosion	no corrosion- polished surface stained by corrosion of 316L S. S.
no corrosion after 100 days	no corrosion after 100 days	heavy pitting, staining and anodic dissolution after 10 days	see crevice corrosion
———	———	———	no corrosion after 100 days
no corrosion after 100 days	no corrosion after 100 days	heavy pitting, staining and anodic dissolution after 10 days	no corrosion after 100 days

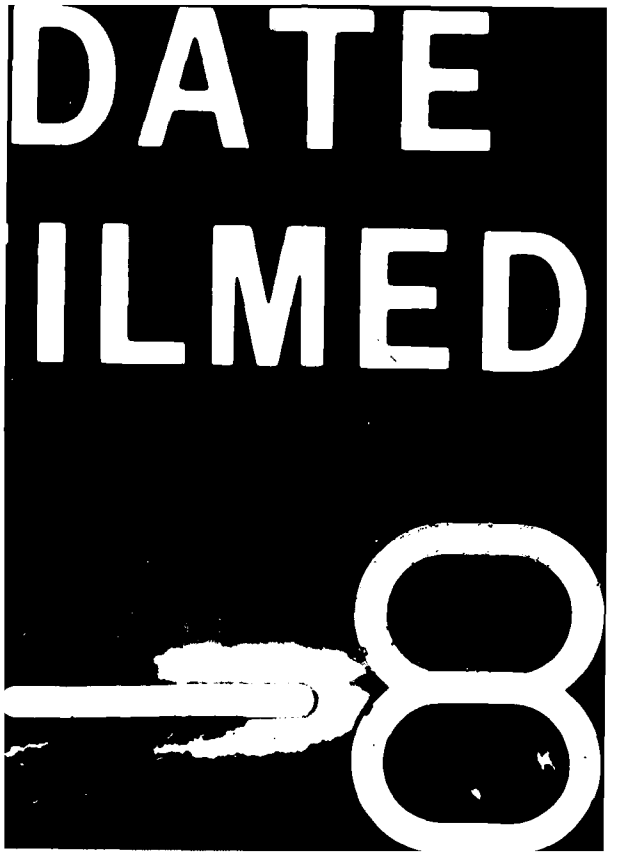
TABLE VII. SUMMARY OF TEST RESULTS

EFFECTS ON PRIMARY MATERIAL

	TITANIUM ALLOY	MULTIPHASE	316L STAINLESS STEEL
UNCOUPLED	a few random pits after 74 days- polished surface preserved	a few random pits after 74 days- polished surface preserved	heavy pitting, staining and corrosion after 50 days
COUPLED WITH GRAPHITE	no corrosion after 100 days	slight corrosion film in small area of sample after 100 days	heavy pitting, staining and corrosion after 10 days
COUPLED WITH TITANIUM ALLOY	see crevice corrosion	no corrosion after 100 days	———
COUPLED WITH MULTIPHASE	no corrosion after 100 days	see crevice corrosion	heavy pitting, staining and anodic dissolution after 10 days
COUPLED WITH 316L STAINLESS STEEL	———	no corrosion- polished surface stained by corrosion of 316L S. S.	see crevice corrosion
COUPLED WITH CAST VITALLIUM	no corrosion after 100 days	no corrosion after 100 days	heavy pitting, staining and anodic dissolution after 10 days
COUPLED WITH WROUGHT VITALLIUM	———	———	———
COUPLED WITH ITSELF (CREVICE CORROSION)	no corrosion after 100 days	no corrosion after 100 days	heavy pitting, staining and anodic dissolution after 10 days

TABLE VIII. SUMMARY OF TEST RESULTS

SCRATCH TEST	EFFECT ON PRIMARY MATERIAL		
	TITANIUM ALLOY	MULTIPHASE	CAST VITALLIUM
COUPLED WITH TITANIUM ALLOY	see crevice corrosion	corrosion film at scratches and indentation burrs after 100 days	corrosion film at indentation burrs after 100 days
COUPLED WITH MULTIPHASE	no corrosion after 100 days	see crevice corrosion	no corrosion after 100 days
COUPLED WITH CAST VITALLIUM	no corrosion after 100 days	no corrosion after 100 days	see crevice corrosion
COUPLED WITH WROUGHT VITALLIUM	———	———	no corrosion after 100 days
CREVICE CORROSION	no corrosion after 100 days	no corrosion after 100 days	corrosion film at indentation burrs after 100 days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